

TO:  
**Mail Stop 8**  
**Director of the U.S. Patent and Trademark Office**  
**P.O. Box 1450**  
**Alexandria, VA 22313-1450**

**REPORT ON THE  
FILING OR DETERMINATION OF AN  
ACTION REGARDING A PATENT OR  
TRADEMARK**

In compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been

filed in the U.S. District Court for the District of Maryland on the following

Patents or

Trademarks:

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT FOR THE DISTRICT OF MARYLAND
MJG-08-1583	6/18/08	
PLAINTIFF	DEFENDANT	
Datasci, LLC	Omnicomm Systems, Inc.	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
6,496,1827 <sup>b2</sup>		
2		
3		
4		
5		

In the above-entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY	<input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above-entitled case, the following decision has been rendered or judgment issued:

DECISION/JUDGMENT

CLERK	(BY) DEPUTY CLERK	DATE
Felicia C. Cannon	Ramona Farrow	 6/19/08

Copy 1—Upon initiation of action, mail this copy to Director    Copy 3—Upon termination of action, mail this copy to Director  
Copy 2—Upon filing document adding patent(s), mail this copy to Director    Copy 4—Case file copy

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND  
(Northern Division)

)  
**DATASCI, LLC**)  
18111 Prince Philip Drive )  
Olney, Maryland 20810, )  
Plaintiff, )  
v. )  
COVANCE INC. )  
210 Carnegie Center )  
Princeton, New Jersey 08540, )  
and )  
**OMNICOMM SYSTEMS, INC.**)  
2101 W. Commercial Boulevard, Suite 4000 )  
Ft. Lauderdale, Florida 33309, )  
Defendants. )  
\_\_\_\_\_  
Civil Action No. 08-cv-01583

**COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff, Datasci, LLC, by counsel, files this complaint against defendants, Covance Inc., and Omnicomm Systems, Inc., and alleges as follows:

1. This is an action for patent infringement under 35 U.S.C. § 1, *et seq.*

**PARTIES**

2. Plaintiff, Datasci, LLC ("Datasci"), is a Maryland limited liability company with offices located at 18111 Prince Philip Drive, Olney, Maryland 20810.
3. Defendant, Covance Inc. ("Covance"), is a Delaware corporation with its office located at 210 Carnegie Center, Princeton, New Jersey 08540.

4. Defendant, Omnicomm Systems, Inc. ("Omnicomm"), is a Delaware corporation with its office located at 2101 W. Commercial Boulevard, Suite 4000, Ft. Lauderdale, Florida 33309.

**JURISDICTION AND VENUE**

5. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Subject matter jurisdiction exists pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Personal jurisdiction over the defendants is proper in this District.

7. Venue exists in this District pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

**BACKGROUND**

8. Datasci owns all title, right, and interest in and to United States Letters Patent No. 6,496,827 ("the '827 patent"), entitled Methods and Apparatus for the Centralized Collection and Validation of Geographically Distributed Clinical Study Data with Verification of Input Data to the Distributed System, which was duly and legally issued by the United States Patent and Trademark Office on December 17, 2002. A copy of the '827 patent is attached as Exhibit A.

9. In order for a new drug or medical device to be marketed in the United States, the drug or device must undergo extensive testing, including clinical trials, and regulatory review to determine that it is safe and effective.

10. A contract research organization ("CRO") is an entity that contracts with a drug or device sponsor to perform one or more of the obligations of that sponsor, such as the design of a protocol, selection or monitoring of investigations, clinical trial management (preclinical through phase IV), evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration.

11. CROs and clinical trial sponsors may use an electronic data capture ("EDC") system to collect, validate and analyze data electronically.

12. Covance, a publicly-traded company, is a CRO that provides drug development services, including clinical trials. Covance uses web-based EDC systems and products in providing services to its customers. Covance has been and is doing business in Maryland and represents that it has an office in Maryland.

13. Omnicomm, a publicly-traded company, represents that it is a healthcare technology company that provides web-based EDC systems and related services to pharmaceutical and biotechnology companies, CROs, academic research institutions and other clinical trial sponsors. It further represents that one of its software products, TrialMaster®, allows clinical trial sponsors and investigative sites to securely collect, validate, transmit, and analyze clinical study data including patient histories, patient dosing, adverse events, and other clinical trial information. Omnicomm has been and is doing business in Maryland and represents that it has an office in Maryland.

**COUNT I**  
**(Patent Infringement by Covance — 35 U.S.C. § 271)**

14. The foregoing allegations of the complaint are incorporated by reference.

15. Covance has and continues to infringe directly, indirectly, contributorily, and/or by inducement, the claims of the '827 patent by making, using, offering to sell, and/or selling products and services in this District and throughout the United States.

16. Covance's acts of infringement will continue unless enjoined by this Court.

17. Covance's acts of infringement have caused and will continue to cause Datasci substantial and irreparable injury for which Datasci is entitled to receive injunctive relief and damages adequate to compensate it for such infringement.

18. Covance has been and is on notice of its infringement of the '827 patent and has continued to engage in such infringing activity.

19. Covance's acts of infringement have been willful and deliberate, rendering this case "exceptional" within the meaning of 35 U.S.C. § 285.

**COUNT II**  
**(Patent Infringement by Omnicomm — 35 U.S.C. § 271)**

20. The foregoing allegations of the complaint are incorporated by reference.

21. Omnicomm has and continues to infringe directly, indirectly, contributorily, and/or by inducement, the claims of the '827 patent by making, using, offering to sell, and/or selling products and services in this District and throughout the United States.

22. Omnicomm's acts of infringement will continue unless enjoined by this Court.

23. Omnicomm's acts of infringement have caused and will continue to cause Datasci substantial and irreparable injury for which Datasci is entitled to receive injunctive relief and damages adequate to compensate it for such infringement.

24. Omnicom has been and is on notice of its infringement of the '827 patent and has continued to engage in such infringing activity.

25. Omnicomm's acts of infringement have been willful and deliberate, rendering this case "exceptional" within the meaning of 35 U.S.C. § 285.

**DEMAND FOR RELIEF**

WHEREFORE, Datasci requests this Court to enter judgment in its favor and against defendants, awarding it the following relief:

A. Permanently enjoining defendants, their officers, agents, servants, employees, and any others acting in concert with them from infringing the '827 patent;

B. Awarding Datasci damages resulting from defendants' acts of infringement and ordering defendants to account for and pay to Datasci damages adequate to compensate Datasci for the infringement of its patent rights, including lost profits;

- C. As a result of defendants' willful acts of infringement, awarding Datasci treble damages pursuant to 35 U.S.C. § 284;
- D. Declaring this case exceptional pursuant to 35 U.S.C. § 285 and awarding Datasci interest, costs, expenses and attorneys' fees; and
- E. Granting Datasci such other relief as the Court deems just and proper.

**JURY DEMAND**

Datasci hereby demands trial by jury as to all issues in this action triable of right by a jury.

Dated: June 18, 2008

Respectfully submitted,

/s/ Richard J. Oparil

Gerard P. Martin (Bar No. 00691)  
ROSENBERG MARTIN GREENBERG, LLP  
25 South Charles Street, Suite 2115  
Baltimore, MD 21201  
(410) 727-6600  
(410) 727-1115 (fax)

Richard J. Oparil (Bar No. 13063)  
PATTON BOGGS LLP  
2550 M Street, NW  
Washington, DC 20037  
(202) 457-6000  
(202) 457-6315 (fax)

Kevin M. Bell (Bar No. 14382)  
PATTON BOGGS LLP  
8484 Westpark Drive  
McLean, VA 22102  
(703) 744-8000  
(703) 744-8001 (fax)

*Attorneys for Plaintiff Datasci, LLC*

*Of Counsel:*

Scott A.M. Chambers, Ph.D.  
PATTON BOGGS LLP  
8484 Westpark Drive  
McLean, VA 22102  
(703) 744-8000  
(703) 744-8001 (fax)